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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,266	02/02/2001	Wayne Woodrow	205,011	9732

7590 09/21/2004

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EXAMINER
AUDET, MAURY A

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/776,266	WOODROW, WAYNE	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-59* is/are pending in the application.

4a) Of the above claim(s) *38-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment and Arguments

Applicant's filing of an amendment and arguments, filed in the RCE of June 28, 2004, are acknowledged. New claims 38-59 are pending and examined on the merits.

Claim Rejections - 35 USC § 112 1st Scope

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of new claims 38-59 (formerly the rejection of claims 1-2, 10-24, and 31-37) under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a range of 3 to 6 mg of citric acid/disodium phosphate dihydrate or 5 to 11 mg of citric acid/trisodium citrate dihydrate (as in former claims 14, 34, 15, and 21; depending from claims 1 and 2 respectively), *does not reasonably provide enablement for any buffer of any mg range*. Applicant's arguments have been considered but are not found persuasive. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

> The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the

> courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement *for any buffer of any mg range* in the pharmaceutical composition for the following reasons:

The nature of the invention: The claimed invention is discussed in the previous action.

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). The specification *only specifically* describes/enables that 3 to 6 mg of citric acid/disodium phosphate dihydrate or 5 to 11 mg of citric acid/trisodium citrate dihydrate, may be used in the invention to create a "stable" composition for small peptides (i.e. oxytocin/vasopressin).

Although Applicant has argued that the specification suggests that other buffers are contemplated in the invention (i.e. p. 11, last ¶ of response, "For maintaining such a pH value (namely 3.5-6, as said immediately before), the composition shall contain a suitable buffer such as, for example, citric acid . . ."). However, this argument goes to that of the withdrawn written description rejection, rather than the present scope of enablement rejection, as Applicant argues. In connection with this argument, Applicant has amended claims 38-39 to include a specific pH range, and argues that one of skill in the art would be enabled to find buffers that work in this

range (and assumedly provide the "stable" composition of the invention). This argument is not persuasive, because it has *not been found where Applicant clearly shows that it is the pH range* that provides the "stability" that is the core of the present invention. Applicant has shown through tests that a few specific buffer combinations provide a unique stability to small peptide compositions of the present invention. Yet, it is unclear whether this "stability" is the result of the pH range or some other synergistic effect, which the buffer combination has endowed upon the compositions of this invention. Particularly in light of the fact that these exact small peptide compositions were previously known in the art to be unstable absent adsorption inhibitors, preservatives, etc. [Note: See previous Office Action, Interview Summary; regarding teachings of Harris and other prior art; as well as Applicant's Response p. 13, ¶3 "Since both, Martindale's Complete Drug Reference" and "Physical Principles of Pharmacy" contain clear warnings as to the susceptibility of small and medium-sized proteins to container wall adsorption (and suggest suitable "preservative" as remedies)"). Absent evidence to the contrary, the only enabled buffers, which provide the "stability" core to the invention (though through unclear chemical attributes), are 3 to 6 mg of citric acid/disodium phosphate dihydrate or 5 to 11 mg of citric acid/trisodium citrate dihydrate. The claims have not been specifically drawn to these buffers at these mg dosages.

The breadth of the claims and the quantity of experimentation needed: The claims are still drawn broadly to a pharmaceutical composition containing any buffer at any mg range (irrespective of the amended pH range). Absent sufficient teachings in the specification or art sufficient to overcome the teachings of unpredictability in the art as to enablement on whether any buffer of any range could work in the present invention to prevent adsorption of the

composition/described peptides, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA
9/20/04

CHRISTOPHER R. TATE
PRIMARY EXAMINER